E. Benefits

Background

Corn is the largest cultivated crop grown in the U.S. in terms of acreage planted and net value. The crop was planted on 79.5 million acres in the year 2000, yielding 10 billion bushels with a net value of $18.4 billion. There are nearly 410 million acres of agricultural land being used to grow crops nationwide, including Conservation Reserve Program lands (USDA/NRI). Corn rootworm (CRW, *Diabrotica* spp.) is one of a spectrum of insect pests that a farmer may choose to control. Other insect pests include cutworms, wireworms, white grubs, flea beetles, seedcorn maggots, black cutworms, and cornborer species. However, CRW is one of the most damaging insect pests of corn and is responsible for economic damages (costs associated with insecticides and crop losses) totaling nearly $1 billion (Gray, 2000). The three CRW control methods have been: use of crop rotation, soil-applied insecticides, and limited use of rescue-treatments for CRW adult beetles.

Event MON 863 corn rootworm-protected corn (MON 863 corn) (vector ZMIR13L) contains the *cry3Bb1* gene that produces the insecticidal crystal protein, Cry3Bb1, and a *nptII* marker gene that encodes neomycyin phosphotransferase II. MON 863 corn is targeted against the corn rootworm (CRW) complex (*Diabrotica* spp.), comprised primarily of the northern corn rootworm (NCRW, *Diabrotica barberi*, Smith and Lawrence), the western corn rootworm (WCRW, *D. virgifera virgifera*, LeConte), the Mexican corn rootworm (MCRW, *D. virgifera zeae*, Krysan and Smith). One additional *Diabrotica* species, the southern corn rootworm (SCRW, *D. undecimpunctata howardi*, Barber) is considered a relatively minor pest of corn that inhabits the southeastern coastal regions of the U.S. CRW (*Diabrotica* spp.) accounts for more chemical pesticide usage on corn than does any other pest. Approximately 28 million acres of corn are infested with CRW. In the year 2000, approximately 8 million pounds of insecticidal active ingredient costing $172 million were applied to 14 million acres of corn targeted to reduce CRW damage. There were approximately 24 million acres of corn treated with insecticides for CRW and other pests (e.g., grubs, maggots, cutworms, wireworms). USDA/NASS figures from 2001 indicate that 9.8 million pounds of insecticide active ingredients registered for CRW control were applied on more than 31% of the planted acres. Left untreated, CRW can cause severe yield loss, typically in the range from 8 to 16 percent, although reductions in yield may be as high as 28%.

Monsanto's public interest documents (Ward 2002 (MRID# 456539-01), Miller 2000 (450297-01)) provide a summary of information about corn rootworm as a pest in corn, current control measures, and the benefits of MON 863 corn. EPA has used Monsanto's submissions, public comments, syndicated marketing research studies and the published literature to perform its public interest finding and benefits assessment of MON 863. Corn insecticide use and current CRW control practices will be discussed in more detail in EPA's review below. Crop rotation, primarily corn rotated with soybean, has been used effectively, in many areas for many years, to help manage CRW damage (Levine and Sadeghi, 1991). However, the emergence of two different behavior changes in NCRW (extended diapause) and WCRW (soybean rotation) have reduced the effectiveness of the traditional corn-soybean rotation. Crop rotation with soybeans is less effective because some CRW can now infest soybeans (WCRW soybean rotational variant) (Levine et al., 1992a) or overwinter for 2 years until corn is planted again (NCRW extended-diapause variant) (Levine et al., 1992b). The spread of the NCRW extended diapause variant and the WCRW soybean variant have increased the number of first year corn acres needing an insecticide treatment.

Resistance has been reported to some CRW adulticides (e.g., methyl parathion and carbaryl) (Meinke et al., 1998; Scharf et al., 1999; Zhu et al., 2001). Adulticides account for about 9% of the use (see Table 4). In addition, use of chemical insecticides against CRW appears to be increasing as other control measures become less effective. Increased use of chemical pesticides, because of CRW adaptation and resistance results in corresponding increases in risk and cost of using the pesticides. Development of resistance also requires a constant search for new control means, including new chemicals. In contrast, there is no known field resistance to Cry3Bb1 protein or any other Cry 3 class proteins. Adoption of insect resistance management strategies designed for MON 863 will also lessen the likelihood of CRW resistance developing to the Cry3Bb1 protein.

All CRW insecticides display a broad spectrum of activity and operate via a neurotoxic mechanism of action. The majority (68%) of these products labeled for CRW control are classified as “Restricted Use.” These include chloroethoxyfos, phorate, terbufos, tefluthrin, and the commercial combination of tebupirimfos and cyfluthrin (Aztec). Most are highly toxic to fish, birds, and other wildlife species. Each year there are confirmed reports of human illness, as well as fish and bird poisonings, associated with the registered chemical insecticide alternatives. Several of the current CRW insecticides are in Agency Special Review (i.e., dimethoate, phorate, and terbufos).

There are no registered microbial Bt pesticide products for the control of corn rootworms. There are microbial Bt pesticides that use Cry3 Bt proteins to control Colorado potato beetle, but Colorado potato beetle is not a pest of corn (not a host). Corn rootworm is not a pest of potatoes (not a host).

MON 863 corn represents a new method for controlling CRW. MON 863 corn was developed using recombinant DNA techniques, so that the corn tissues produce the Cry3Bb1 protein that is specifically toxic to CRW. In reviewing the available information, EPA considered in its review the following categories of potential benefits of a MON 863 corn based control strategy for CRW infestations.

- Safer for handlers, applicators, farmers, and the public than chemical alternatives in current use,

- Safer for the environment than current chemical alternatives
- Practical–easier and safer for growers to use than current chemical alternatives
- Comparable or greater efficacy than current chemical alternatives
- Yield benefits
- Reduced use of higher risk chemical alternatives
- Economic benefits to growers

PUBLIC INTEREST FINDING (MRID#s 456530-01 and 450297-01)

The criteria for a determination as to whether registration of a pesticide chemical is in the public interest are set forth in a 1986 Federal Register Notice entitled *Conditional Registration of New Pesticides*, 51 Fed. Reg. 7628 (Mar. 5, 1986). In accordance with this FR Notice, there is a presumption that conditional registration of a pesticide is in the public interest if one of the following criteria is met: (i) the use is for a minor crop; (ii) the use is a replacement for another pesticide that is of continuing concern to the Agency; (iii) the use is one for which an emergency exemption under FIFRA Section 18 has been granted for lack of an alternative pest control method, or (iv) the use is against a pest of public health significance. (Section IV.A. of the FR Notice). Notwithstanding whether a registration of a pesticide chemical may be presumed to be in the public interest, EPA may determine that such a registration is in the public interest on the basis of the following criteria: (i) there is a need for the new chemical that is not being met by currently registered pesticides; (ii) the new pesticide is comparatively less risky to health or the environment than currently registered pesticides; or (iii) the benefits (including economic benefits) from the use of the new active ingredient exceed those of alternative registered pesticides and other available non-chemical techniques. (Section IV.B. of the FR Notice). EPA determines that conditional registration of MON 863 is in the public interest currently used for CRW control that are of continuing concern to the Agency as indicated by the following factors.

1. **Special review.** Certain pesticides that are used for CRW control have been reviewed under EPA Special Review as described at 40 CFR section 154 because the use of these pesticides may result in unreasonable adverse effects to humans or the environment. The pesticides in this category are: dimethoate, phorate, and terbufos. Terbofos and phorate are being evaluated for reregistration.

2. **Acute avian risk from granular pesticides.** EPA issued in 1992 the "Comparative Analysis of Acute Avian Risk from Granular Pesticides"(EPA, 1992). This analysis indentifed 14 granular pesticides that the Agency believed posed potentially higher risk of killing birds due to the higher acute toxicity and availability in the environment. Among these granular pesticides are several that are still in use for CRW control: carbofuran (no longer used as a granular, but still a pesticide of Agency concern), phorate, terbufos, and chlorpyrifos. The results of the Agency's initiative to reduce exposure to these highly toxic granular pesticides is presented in the 1994 EPA report "Avian Granular Risk Reduction Initiative" (EPA, 1994).

3. **Restricted use.** Many of the granular pesticides used for CRW control have been classified as restricted use due to adverse environmental effects under use practices (40 CFR 152.171(a)) that limits the use of these chemicals to certified pesticide applicators. These include chloroethoxyfos, phorate, terbufos, tefluthrin, and the commercial combination of tebupirimfos and cyfluthrin (Aztec).

4. **Food Quality Protection Act of 1996.** EPA must reassess all existing tolerances to be sure that they meet the standard of "reasonable certainty of no harm." The EPA is required to consider first those pesticides that pose the highest risk to humans. EPA is reviewing the organophosphate and carbamate pesticides because of their known risk of acute and chronic toxicity to humans as well as wildlife. The organophosphates and carbamates share the same mode of action. The organophosphate insecticides used for CRW control include: chlorpyrifos, terbufos, phorate, chloroethoxyfos, dimethoate, and tebupirimphos. Carbofuran is used for CRW control and is in the carbamate family.

In addition, EPA also determines, in accordance with the criteria set forth in section IV.B. of the FR Notice, that MON 863 corn qualifies for a positive public interest finding. To qualify under part IV.B, the product must demonstrate advantages in terms of the need for the chemical, its comparative benefits, risks, and costs. Monsanto has submitted two public interest documents (PIDs) and other supporting documents that present the potential benefits of the MON 863 corn product: MRID#s: 450297-01 and 456530-01 – both public interest documents; MRID# 456530-02, Yield Benefit of Corn Event MON 863; MRID# 456430-03, Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials; MRID # 455382-08, Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (*Diabrotica barberi*), Southern Corn Rootworm (*D. undecimpunctata howardi*), and Western Corn Rootworm (*D. virgifera virgifera*); MRID# 456923-01, An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology – YieldGard® Rootworm. Additional information related to grower adoption of MON 863 corn is presented in An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product, MRID# 455770-01. EPA has reviewed the submitted documents, public comments, syndicated marketing research studies and published information. The potential benefits have been identified and evaluated.

The major proposed benefits of MON 863 corn for CRW control are:

- Safer for handlers, applicators, growers, and the public than current chemical alternatives
- Safer for the environment than use of available chemical pesticides
- Easier and less time consuming for farmers to use than current control options
- Comparable or improved efficacy relative to the current chemical alternatives
- Yield benefits
- Reduced use of current higher risk chemical alternatives

♦ Economic benefits to farmers from increased yields and decreased cost of rootworm control as compared with conventional control

Based upon this review, the use of MON 863 CRW-protected corn is presumed to be in the public interest under section IV.A. of 52 FR 7628 because it will replace or reduce the use of a number of higher risk pesticides for CRW control that are of Agency concern as discussed above (e.g., terbufos, chlorpyrifos, phorate). It also has clearly identified benefits and meets the criteria in part IV.B of the FR notice. Therefore, EPA concludes that the use of MON 863 CRW-protected corn is in the public interest and supports the conditional registration under FIFRA section 3(c)(7)(C).

EPA REVIEW OF THE BENEFITS OF MON 863

1. Characterization and use of chemical insecticides to control Corn Rootworm (CRW)

Three CRW control methods have been used for decades: crop rotation (typically with soybeans), soil-applied insecticides to control larvae (approximately 90% of the total CRW treated acres), and use of adulticides to control CRW adult beetles (approximately 10% of the total CRW treated acres) (Levine and Oloumi-Sadeghi, 1991). Greater than 90% of the growers use soil-applied insecticides applied at planting to control larvae due to greater efficacy and ease of application. Historically, crop rotation has been the primary method of controlling CRW (Levine and Oloumi-Sadeghi, 1991). However, crop rotation is now far less effective because of the existence of a WCRW soybean rotational variant primarily in Eastern Illinois and Western Indiana, that colonizes soybeans (Levine and Oloumi-Sadeghi, 1991; Levine et al., 1992a) and of a NCRW extended diapause (2 year extended) variant, primarily in parts of Minnesota, Iowa, and South Dakota (Krysan et al., 1996; Levine et al., 1992b). In addition, CRW has developed resistance to methyl parathion and carbaryl, both adulticides used in rescue treatments (Meinke et al., 1998). Therefore, growers have become increasingly dependent on chemical pesticides to limit CRW losses. EPA has registered 36 insecticide products for control of CRW. These are listed in Table 1. The insecticides used to control corn rootworm in conventionally grown (non-Bt) corn consist mainly of organophosphates (9), carbamates (3), synthetic pyrethroids (6), and phenyl pyrazole (1) classes of chemistry. Twenty-five products are classified as "restricted use." All 36 insecticides are toxic to extremely toxic to fish, aquatic invertebrates, bees, and/or wildlife. Three products have been involved in the Agency's Special Review Process: terbufos, dimethoate, and terbufos. Twenty-six of these products contain active ingredients either from the organophosphate or carbamate classes, both of which are considered to be top priorities under FQPA and tolerance reassessment. Terbufos, phorate, chlorpyrifos, diazinon, ethoprop, carbofuran, and methomyl have presented varying levels of concern regarding avian, aquatic, and mammalian risk. EPA has specified specific risk mitigation measures for all of these chemicals and, in many cases, certain uses have been eliminated because of either human or environmental risk concerns.

Table 1. Insecticide end-use products registered by EPA for use on corn for control of corn rootworm species (Reprinted from p. 18-21, Ward 2002, MRID# 456530-01 and verified by EPA).

Product	Active Ingredients	Type [a]	Use Rate [b]	Use	Classification [c]
Ambush® Insecticide - Syngenta	permethrin – 25.6%	SP	0.2 lb/ac	Adult control	**WARNING. Restricted Use**; extremely toxic to fish and aquatic invertebrates, highly toxic to bees
Asanaâ XL Insecticide 0.66 Emulsifiable Concentrate - DuPont	esfenvalerate – 8.4%	SP	0.05 lb/ac	Adult control	**WARNING. Restricted Use**; extremely toxic to fish and aquatic invertebrates, highly toxic to bees
Aztec® 2.1% Granular Insecticide – Bayer Corp.	tebupirimfos – 2.0% cyfluthrin – 0.1%	OP SP	0.15 lb/ac 0.01 lb/ac	Larval control	**WARNING. Restricted Use**; toxic to fish and wildlife
Baythroid® 2 Emulsifiable Pyrethroid Insecticide - Bayer	cyfluthrin – 25%	SP	0.04 lb/ac	Adult control	**DANGER. Restricted Use**; extremely toxic to fish and aquatic invertebrates, highly toxic to bees, may cause allergic skin reactions
Capture® 2EC Insecticide/Miticide – FMC Corp.	bifenthrin – 25.1%	SP	0.3 lb/ac	Larval control	**WARNING. Restricted Use**; extremely toxic to fish and aquatic invertebrates, highly toxic to bees
Chlorfos® 15G Insecticide Granular – Griffin LLC	chlorpyrifos – 15%	OP	2.02 lb/ac	Larval control	**CAUTION.** Toxic to birds and wildlife, extremely toxic to fish and aquatic organisms
Chlorfos® 4E Insecticide – Griffin LLC	chlorpyrifos – 42%	OP	2.52 lb/ac	Adult & Larval control	**WARNING.** Toxic to birds and wildlife, extremely toxic to fish and aquatic organisms
Counter® CR Systemic Insecticide-Nematicide – American Cyanamid Company	terbufos – 20%	OP	1.30 lb/ac	Larval control	**DANGER. Restricted Use**; fatal if swallowed, inhaled or absorbed through skin, extremely toxic to fish and wildlife
D-z-n® diazinon AG500	diazinon – 48%	OP	0.48 lb/ac	Adult	**CAUTION. Restricted Use**; highly toxic to birds, fish

Product	Active Ingredients	Type [a]	Use Rate [b]	Use	Classification [c]
Insecticide - Syngenta				control	and other wildlife, highly toxic to bees
D-z-n® diazinon AG600 WBC Insecticide - Syngenta	diazinon - 56%	OP	0.45 lb/ac	Adult control	**CAUTION. Restricted Use;** highly toxic to birds, fish and other wildlife, highly toxic to bees
Declare® Emulsifiable Insecticide Concentrate – Griffin LLC	methyl parathion – 45.11%	OP	0.22 lb/ac	Adult control	**DANGER. Restricted Use**: fatal if swallowed, inhaled or absorbed through skin, highly toxic to aquatic invertebrates and wildlife, highly toxic to bees
Diazinon 500-AG Organophosphate Insecticide – UAP	diazinon – 48%	OP	0.48 lb/ac	Adult control	**CAUTION. Restricted Use;** highly toxic to birds, fish and other wildlife, highly toxic to bees
Dimethoate 4 EC Systemic Insecticide - Helena	dimethoate – 44.8%	OP	0.45 lb/ac	Adult control	**WARNING.** Toxic to wildlife and aquatic invertebrates, highly toxic to bees
Dimethoate 400 Systemic Insecticide-Miticide - UAP	dimethoate – 43.5%	OP	0.44 lb/ac	Adult control	**WARNING.** Toxic to wildlife and aquatic invertebrates, highly toxic to bees
5 lb. Dimethoate Systemic Insecticide - Helena	dimethoate – 57%	OP	0.46 lb/ac	Adult control	**DANGER.** Toxic to wildlife and aquatic invertebrates, highly toxic to bees
Force® 3G Insecticide - Syngenta	tefluthrin – 3%	SP	0.17 lb/ac	Larval control	**CAUTION. Restricted Use**; very highly toxic to freshwater and estuarine fish and invertebrates
Fortress® 2.5G granular insecticide - DuPont	chlorethoxyfos – 2.5%	OP	0.16 lb/ac	Larval control	**DANGER. Restricted Use**; toxic to wild mammals, birds, fish and aquatic invertebrates
Fortress® 5G granular insecticide – DuPont	chlorethoxyfos – 5%	OP	0.16 lb/ac	Larval control	**DANGER. Restricted Use**; toxic to wild mammals, birds, fish and aquatic invertebrates

Product	Active Ingredients	Type [a]	Use Rate [b]	Use	Classification [c]
Furadan® *4F insecticide/ nematicide* – FMC Corp.	carbofuran – 44%	C	0.88 lb/ac	Adult & larval control	**DANGER. Restricted Use**; poisonous if swallowed or inhaled, toxic to fish, birds and other wildlife, highly toxic to bees, can seep or leach through soil and can contaminate groundwater
Lannate® *LV insecticide* – DuPont	methomyl – 29%	C	0.65 lb/ac	Adult control	**DANGER. Restricted Use**; fatal if swallowed, toxic to fish, aquatic invertebrates and mammals, highly toxic to bees, known to leach through soil into groundwater
Lannate® *SP insecticide* - DuPont	methomyl – 90%	C	0.45 lb/ac	Adult control	**DANGER. Restricted Use**; fatal if swallowed, may cause blindness, toxic to fish, aquatic invertebrates and mammals, highly toxic to bees, known to leach through soil into groundwater
Lorsban® *15G Granular Insecticide* – Dow Agrosciences	chlorpyrifos – 15%	OP	2.03 lb/ac	Larval control	**CAUTION.** Toxic to birds and wildlife, extremely toxic to fish and aquatic organisms
Lorsban® *-4E Insecticide*– Dow Agrosciences	chlorpyrifos – 44.9%	OP	2.69 lb/ac	Adult & larval control	**WARNING.** Toxic to birds and wildlife, extremely toxic to fish and aquatic organisms
Mocap® *10% Granular Nematicide Insecticide* – Aventis CropScience	ethoprop – 10%	OP	3.53 lb/ac	Larval control	**WARNING.** Toxic to aquatic organisms and wildlife

Product	**Active Ingredients**	**Type** [a]	**Use Rate** [b]	**Use**	**Classification** [c]
Mocap® *EC Nematicide-Insecticide* – Aventis CropScience	ethoprop – 69.6%	OP	3.34 lb/ac	Larval control	**DANGER. Restricted Use**; toxic to aquatic organisms and extremely toxic to birds
Penncap-M® Microencapsulated Insecticide – Elf Atochem	methyl parathion – 22%	OP	0.44 lb/ac	Adult control	**WARNING. Restricted Use**; highly toxic to aquatic invertebrates and wildlife
Phorate 20 G Organophosphate Insecticide - UAP	phorate – 20%	OP	1.3 lb/ac	Adult & larval control	**DANGER. Restricted Use**; extremely toxic to fish and wildlife
Pounce® WSB Insecticide – FMC Corporation	permethrin - 24.7%	SP	0.2 lb/ac	Adult control	**WARNING. Restricted Use**; extremely toxic to fish and aquatic invertebrates, highly toxic to bees
Pounce® 3.2 EC Insecticide – FMC Corporation	permethrin – 38.4%	SP	0.2 lb/ac	Adult control	**CAUTION. Restricted Use**; extremely toxic to fish and aquatic invertebrates, highly toxic to bees
Pounce® 25 WP Insecticide – FMC Corporation	permethrin – 25%	SP	0.2 lb/ac	Adult control	**WARNING. Restricted Use**; extremely toxic to fish and aquatic invertebrates, highly toxic to bees
Regent® 4 SC Insecticide – Aventis CropScience	fipronil – 39.4%	PP	0.13 lb/ac	Larval control	**WARNING. Restricted Use**; toxic to birds, fish and aquatic invertebrates
Sevin® brand 80S Carbaryl Insecticide – Aventis CropScience	carbaryl – 80%	C	2.0 lb/ac	Adult control	**WARNING.** Extremely toxic to aquatic and estuarine invertebrates, highly toxic to bees
Sevin® brand XLR PLUS Carbaryl Insecticide – Aventis CropScience	carbaryl – 44.1%	C	1.76 lb/ac	Adult control	**CAUTION.** Extremely toxic to aquatic and estuarine invertebrates, highly toxic to bees

Product	Active Ingredients	Type [a]	Use Rate [b]	Use	Classification [c]
Thimet® 20-G Soil and Systemic Insecticide – American Cyanamid	phorate – 20%	OP	1.3 lb/ac	Larval control	**DANGER. Restricted Use**; extremely toxic to fish and wildlife
Thimet® 20-G Soil and Systemic Insecticide – American Cyanamid	phorate – 20%	OP	1.3 lb/ac	Larval control	**DANGER. Restricted Use**; extremely toxic to fish and wildlife
Warrior® Insecticide with Zeon Technology - Syngenta	lambda-cyhalothrin – 11.4%	SP	0.03 lb/ac	Adult control	**WARNING. Restricted Use**; extremely toxic to fish and aquatic organisms and toxic to wildlife, highly toxic to bees

a - OP: organophosphate; SP: synthetic pyrethroid; C: carbamate; PP: phenyl pyrazole
b – maximum labeled use rate expressed in pounds of active ingredient per acre (assume that 1 liq pt ≅ 1 lb)
c – precautionary language as stated on label

In the year 2000, approximately 8 million pounds of insecticidal active ingredient costing $172 million were applied to 14 million acres of corn targeted to reduce CRW damage (see Table 2 below). These data were independently verified by EPA. There were approximately 24 million acres of corn treated with insecticides. Growers indicated that CRW was the sole target pest on approximately 7 million acres and one of a number of pests on the remaining treated acres. CRW-targeted acres (14 million) that received an insecticide treatment represented 18% of the total acres of corn planted in the continental U.S. and 59% of the total acres receiving any insecticide treatment in 2000. Continuous corn and first year corn acres (rotated acres) received 58% and 42% of the CRW-target insecticide applications, respectively. Continuous corn use areas include western Iowa, Nebraska, eastern Colorado, eastern South Dakota, the panhandle areas of Texas and Oklahoma, northeastern New Mexico, and southern Minnesota. Rotational acres are located predominantly in eastern Iowa, most of Minnesota, Wisconsin, Missouri, Illinois, Indiana, Michigan and other areas of the Eastern corn belt.

The 14 million acre treatments does not include acreage where the expected level of infestation is below the economic threshold, that is, where the expected loss is less than the $15.00 cost of treatment. National estimates of infested acreage are not published (unlike the Cotton Council for example that publishes estimates of infested acreage). Market analyses estimate all infested acreage with CRW to be around 28 million acres. This estimate is reasonable with what could be expected on the basis of yield losses without treatment and prices in year 2000. At depressed corn prices of $2 per bushel, yields at 175 bu/acre, a maximum yield loss of 8.5% would result in a $30 loss. Half of infested acres would be below the $15.00 cost of treatment. If corn prices rise or the cost of control decreases, the percent of infested acres that is treated would likely increase.

The infested acreage is expected to grow by 2.6% per year which implies that the 28 million in year 2000 will grow to 39 million acres by the year 2013. These factors needs to be considered when projecting the amount of chemical acre treatments and adopted acres of MON 863.

Table 2. Insecticide usage on corn in year 2000 reprinted from Ward 2002, MRID# 456530-01, p. 22

Parameter	Continuous Corn	First Year Corn	All Corn
Acres planted (x1,000)	22,269	57,310	79,579
Total insecticide treated acres (x1,000)	11,590	12,518	24,108
Total insecticide a.i. applied (lb x1,000)	6,332	6,011	12,343
CRW-targeted acres (x1,000)	**8,271**	**5,926**	**14,197**
a.i. applied to CRW-targeted acres (lb x1,000)	4,699	3,137	7,836
Average a.i. rate applied (lb/ac)	0.568	0.529	0.552
Average cost per acre	$11.95	$12.27	$12.08
Total cost of CRW insecticide purchased (x1,000)	$98,811	$72,699	$171,510

Only a few of the 36 products listed in Table 1 that are registered for control of CRW dominate the market. Table 3 below shows that five active ingredients, tefluthrin, chlorpyrifos, terbufos, fipronil, cyfluthrin/tebupirimfos, are applied to 86% of the acres treated. Three of these active ingredients are organophosphates and three are classified as restricted use. In terms of pounds of insecticide applied, chlorpyrifos and terbufos (both organophosphates), account for 77% of the total insecticide products (almost 6 million pounds) applied to CRW-targeted acres. These 11 active ingredients (in Table 3) accounted for 98.3% of the total quantity of insecticide applied to CRW-target acres in 2000.

Table 3. Insecticide active ingredients applied to corn rootworm-targeted acres in year 2000 reprinted from p. 24, Ward 2002, MRID# 456530-01

Active Ingredient	Acres Treated (X 1,000)	Pounds Applied (Formulated Product)
Carbofuran	342	242,379
Chlorethoxyfos	361	55,485
Chlorpyrifos	**3,557**	**3,765,310**
Cyfluthrin/Tebupirimfos	1,326	179,527
Fipronil	1,498	158,141
Lambda-cyhalothrin	179	3,846
Methyl parathion	367	142,011
Permethrin	246	24,344
Phorate	508	588,380
Tefluthrin	3,570	400,339
Terbufos	2,044	2,146,761
Total	13,998	7,706,523

Table 4 provides a listing of the 13 major end-use products that are applied to CRW-targeted areas (Table 1 lists end-use products that are labeled for CRW control). The use of five products, Aztec 2.1% Granular Insecticide, Counter CR Systemic Insecticide-Nematicide, Force 3G Insecticide, Lorsban 15G Granular Insecticide, and Regent 4 SC Insecticide accounted for applications to 83% of the CRW-targeted areas. These products are all for larvicide rather than adulticide use. All of these products are restricted use except Lorsban 15G Granular Insecticide. A small number of seed-applied insecticides have been recently approved for use: Gaucho seed-applied insecticide (Gustafson, LLC), Prescribe seed-applied insecticide (Gustafson, LLC), and Force ST seed-applied insecticide (Syngenta). Imidacloprid is the active ingredient in Gaucho and Prescribe. Tefluthrin is the active ingredient in Prescribe. Ward (2002) describes that the performance of these seed-applied insecticides is inconsistent and weak under conditions of high CRW pressure and that these products do not perform as well as most soil-applied insecticides.

Table 4. Insecticide end-use products used for control of corn rootworm in year 2000 reprinted from p. 25, Ward 2002, MRID# 456530-01

Product[a]	Average Cost ($/A)	Adult (A)/Larval (L) Control	EPA Classification	Acres Treated (X 1,000)
Aztec 2.1% Granular Insecticide **(tebupirimfos/cyfluthrin)**	**$13.05**	**L**	**Restricted**	**1327**
Counter CR Systemic Insecticide-Nematicide **(terbufos)**	**$13.10-$13.50**	**L**	**Restricted**	**2,044**
Force 3G Insecticide **(tefluthrin)**	**$14.48**	**L**	**Restricted**	**3,570**
Fortress 5G granular insecticide **(chlorethoxyfor)**	**$14.65**	**L**	**Restricted**	**361**
Furadan 4F insecticide/ nematicide **(carbofuran)**	**$11.74**	**L**	**Restricted**	**342**
Lorsban 15G Granular Insecticide **(chlorpyrifos)**	**$11.79**	**L**	**Unrestricted**	**3,165**
Lorsban 4E Insecticide **(chlorpyrifos)**	**$10.52**	**A**	**Unrestricted**	**374**

Product[a]	**Average Cost ($/A)**	**Adult (A)/Larval (L) Control**	**EPA Classification**	**Acres Treated (X 1,000)**
Penncap-M Microencapsulated Insecticide **(methyl parathion)**	**$6.79**	**A**	**Restricted**	**330**
Pounce 3.2 EC Insecticide **(permethrin)**	**$4.42**	**A**	**Restricted**	**224**
Regent 4 SC Insecticide **(fipronil)**	**$14.65**	**L**	**Restricted**	**1,392**
Regent 80 WG Insecticide **(fipronil)**	**$8.57**	**L**	**Restricted**	**106**
Thimet 20-G Soil and Systemic Insecticide **(phorate)**	**$10.90-$12.74**	**L**	**Restricted**	**508**
Warrior Insecticide with Zeon Technology **(Lambda-cyhalothrin)**	**$7.37**	**A**	**Restricted**	**173**
Total				
Adult Control	**$4.42 – $10.52**			**8%**
Larval Control	**$8.57 - $14.65**			**92%**
Restricted Use				**73%**
Unrestricted				**27%**

a - active ingredient(s) stated in parentheses.

2. Comparative toxicity to humans (MRID#s 456530-01 and 450297-01)

MON 863 CRW-protected corn is safer for handlers, applicators, farmers, and the public than chemical pesticides in current use. Adoption of MON 863 corn hybrids will reduce the occupational, farmer, and public risks associated with the manufacture, transportation, storage, handling, application, and disposal of conventional insecticides. Many comments were received concerned with the potential contact to growers, their families and communities with the application, drift and on-farm storage of toxic materials. At product maturity, MON 863 hybrids have the potential to reduce insecticide applications by millions of pounds. This reduction of insecticide use will lead to both reduced human and environmental risks. The potential insecticide use reduction caused by adoption of MON 863 corn hybrids is discussed in section 7) below.

Virtually all of the registered conventional insecticides used to control CRW are of special concern to EPA because of risks to humans (see Table 1 and discussion on Public Interest Finding above). Of the 36 registered insecticides for CRW control listed in Table 1, 25 are classified as “Restricted Use” and 12 have the “Danger” label classification. These include products formulated with the following active ingredients: chloroethoxyfos, phorate, terbufos, tefluthrin, and the commercial combination of tebupirimfos and cyfluthrin (Aztec). Each year there are confirmed reports of human illness associated with the registered chemical insecticide alternatives (See Agency’s Incident Data Base, http://www.opp.gov/pesticides). Several of the current CRW insecticides are in Agency Special Review (i.e., dimethoate, phorate, and terbufos). Twenty-six of the 36 products contain either organophosphate and carbamate active ingredients that are listed as top priorities for tolerance reassessment under FQPA because of their high risk to humans and the environment. Because of EPA’s concern with the conventional insecticide alternatives for CRW control, special precautions are required during all stages of their life cycle, including manufacture, transportation, storage, use, and disposal.

By contrast, MON 863 corn presents minimal or no risks to humans during any stage of its life cycle, from production to ingestion to disposal. Cry3Bb1protein has no toxic effects on mammals, and is not likely to induce allergic or hypersensitive responses based on results in all appropriate tests. Use of this new pesticide could potentially reduce use of CRW chemical pesticides by millions of pounds per year.

All of the conventional insecticide alternatives require a tolerance (maximum allowable level of pesticide residue in food). In contrast, the Agency has exempted the Cry3Bb1 protein and the genetic material necessary for its production in corn from the requirement for a tolerance, based on its human and animal safety (EPA, 2001). Based on the Agency’s review provided early in this document, MON 863 corn presents no unreasonable risks to humans during any stage of its life cycle, from production, handling, storage, ingestion, to disposal. Cry3Bb1protein has no toxic effects on mammals, and is not likely to induce allergic or hypersensitive responses based on results in all appropriate tests. In addition, use of this new pesticide could potentially reduce the use of CRW chemical pesticides by millions of pounds per year and substantially reduce mammalian risk.

3. Comparative toxicity and potential for adverse environmental effects (MRID#s 456530-01 and 450297-01)

All of the major chemicals used for CRW control can cause major adverse environmental effects under conditions of normal use (see Table 1 and the discussion in the Public Interest Finding section above). These products are formulated with the following active ingredients: chlorethoxyfos, phorate, terbufos, tefluthrin, methyl parathion, carbofuran, fipronil, bifenthrin, cyfluthrin, esfenvalerate, permethrin, diazanon, chlorpyrifos, dimethoate, methomyl, ethoprop, carbaryl, lambda-cyhalothrin, and the commercial combination of tebupirimfos and cyfluthrin (Aztec). Fifteen products are labeled as “toxic,” 6 as “highly toxic,” 1 as “very highly toxic,” and 14 as “extremely toxic” to birds, fish and other wildlife. Each year there are confirmed reports of fish and bird poisonings associated with the registered chemical insecticide alternatives. Environmental effects from CRW chemical pesticides include toxicity and mortality in fish, birds, terrestrial mammals, aquatic invertebrates, and non-target insects. These chemicals can also spread via spray drift and runoff, thus contaminating both land and water bodies and impacting non-target organisms. Of the 36 registered insecticides for CRW control listed in Table 1, 25 are classified as “Restricted Use” and 12 have the “Danger” label classification. Table 5 below, compared the ecological risk for selected endpoints for the three top CRW insecticides: terbufos, chlorpyrifos, and tefluthrin. Together these three insecticides account for 63% of the acres treated (see Table 4 above). Tefluthrin poses lower risk than either chlorpyrifos or terbufos (see Table 5 below).

Table 5. Comparison of ecological risks associated with terbufos, chlorpyrifos, and tefluthrin.

Endpoint	Terbufos[a]	Chlorpyrifos[a]	Tefluthrin[a]
Mammalian Acute RQ	50	1	0.008
Avian Acute RQ	0.27	0.55	0.0001
Fish acute RQ	11	2	0.77
Freshwater invertebrates RQ	50	20	0.77
Marine/Estuarine Invertebrates RQ	53	162	0.87

[a]Risk is defined as the risk quotient (RQ)> level of concern (LOC). RQ = Toxicity/Exposure. LOC = 1

Potential adverse effects on non-target organisms resulting from the exposure to Cry3Bb1 have been evaluated in a series of studies with representative avian, aquatic, and terrestrial beneficial invertebrate species as described previously in this document.

Table 6. Summary of results from ecological effects tests with Cry3Bb1 proteins. (Reprinted from p. 35, Ward, 2002 (MRID#456530-01)) Note: risk conclusions are based on protein concentrations measured in plant tissues of corn event MON 863 (Dudin et al., 2001 and verified by EPA).

Test Organism	Test Substance	Results [a]	Conclusions [b]	Reference
Cladoceran (*Daphnia magna*)	Pollen	NOEC ≥ 2.26 µg/l	NOEC ≥141x surface water MEEC	Drottar and Krueger, 1999
Collembola (*Folsomia candida*)	Leaf	NOEC ≥ 872.5 µg/g	NOEC ≥66x soil MEEC	Teixeira, 1999
Channel Catfish (*Ictalurus punctatus*)	Grain	No effect on growth or survival at 35% of diet	No significant risk	Li and Robinson, 1999
Bobwhite Quail (*Colinus virginianus*)	Grain	No effect on growth or survival at 10% of diet	No significant risk	Gallagher *et al.*, 1999
Adult Honey Bee (*Apis mellifera*)	Purified protein	NOEC ≥360 µg/ml	NOEC ≥3.8x maximum pollen level	Maggi, 1999a
Larval Honey Bee (*Apis mellifera*)	Purified protein	NOEC ≥1790 µg/ml as a single dose	NOEC ≥19x maximum pollen level	Maggi, 1999b
Adult Ladybird Beetle (*Hippodamia convergens*)	Purified protein	NOEC ≥8000 µg/g	NOEC ≥86x maximum pollen level	Palmer and Krueger, 1999c

Test Organism	Test Substance	Results [a]	Conclusions [b]	Reference
Adult Ladybird Beetle (*Hippodamia convergens*)	Pollen	No effect on growth or behavior at 50% of diet	No significant risk	Bryan *et al.*, 2001
Larval Ladybird Beetle (*Coleomegilla maculata*)	Pollen	No effect on growth or survival at 50% of diet	No significant risk	Duan *et al.*, 2001a
Adult Ladybird Beetle (*Coleomegilla maculata*)	Pollen	No effect on survival at 50% of diet	No significant risk	Duan *et al.*, 2001b
Monarch Butterfly Larvae (*Danus plexippus*)	Pollen	No effect on growth or survival	No significant risk	Sears and Mattila, 2001
Green Lacewing Larvae (*Chrysoperla carnea*)	Purified protein	NOEC ≥ 8000 μg/g	NOEC ≥ 86x maximum pollen level	Palmer and Krueger, 1999a
Parasitic Hymenoptera (*Nasonia vitripennis*)	Purified protein	NOEC = 400 μg/ml	NOEC ≥ 4.3x maximum pollen level	Palmer and Krueger, 1999b
Earthworm (*Eisenia fetifa*)	Purified protein	NOEC = 57 mg/kg	NOEC ≥ 4.3x MEEC in soil	Hoxter *et al.*, 1999

[a] NOEC- No Observable Effect Concentration
[b] MEEC- Maximum Expected Environmental Concentration

Results of the environmental fate studies indicate that the Cry3Bb1 protein does not accumulate in the environment (e.g., air, soil, water), or in animal tissues. Therefore, non-target soil organisms will be minimally exposed to the Cry3Bb1 protein based on the rapid degradation of Cry3Bb1 in soil.

In summary, Cry3Bb1 poses less risk to the environment than tefluthrin, terbufos, chlorpyrifos, fipronil or any other conventional insecticide labeled for CRW control. MON 863 corn poses minimal risk to non-target organisms. The Cry3Bb1 protein is expressed by the corn plant; thus, reducing the exposure to non-target organisms. In addition, Cry3Bb1 has a narrow target range. Monsanto has performed dietary bioassays to determine the insecticidal spectrum of the Cry3Bb1 protein. The protein is effective at killing only beetles of the family Chrysomelidae, specifically CRW and Colorado potato beetle (*Leptinotarsa decemlineata (Say)*). There have been no functional receptors for Cry proteins found on intestinal cells of fish, birds, or mammals (Ward, 2002). In addition, Cry3Bb1 is degraded rapidly in the soil (reducing non-target exposure). Use of this new pesticide could potentially reduce the use of CRW chemical pesticides by millions of pounds per year and substantially reduce non-target organism risk.

4. Practical–easier and safer for growers to use than current alternatives (MRID#s 456530-01 and 450297-01)

MON 863 corn offers many practical advantages to corn growers than the current alternatives. It can be planted early for a longer growing season and potentially higher yield, while ensuring adequate CRW protection throughout the growing season. Early planting corn is desirable to boost yield, but it can also reduce insecticide performance because of chemical dissipation prior to larval hatch. With MON 863 corn, the grower can plant early and not have to worry about timing or chemical dissipation. In addition, growers should be able to plant their crop more quickly because they won't have to continually have to stop and refill the insecticide boxes. MON 863 seeds can also have seed treatments that will allow even greater control of other associated pests such as wireworm, grub, maggots, and cutworms. Thus, growers will have multi-pest protection while carrying out insect control in essentially a single step at planting. All of these advantages to planting MON 863 corn are practical, easier, and safer for the grower. Planting MON 863 corn will save the grower money in application, insecticide, labor, fuel, equipment, storage and disposal costs (since there will be no insecticide containers needed for CRW control). Plus, it will provide the grower and other occupational workers greater safety, protect water bodies from run-off, and mitigate spray-drift and non-target effects. Grower interest in MON 863 is high, approximately 70% of growers survived were either "very interested" or "somewhat interested" in the new CRW trait hybrids (Vaughn et al., 2002, p. 48). However, in the first few years there will be limited amount of seeds available, the trait will not be in all corn varieties, and many growers will try out the new technology rather than planting the maximum 80% of corn with MON863.

The three CRW control methods have been use of crop rotation and soil-applied insecticides, with limited use of rescue-treatments for CRW adult beetles. Historically, crop rotation has been the primary method of controlling CRW (Levine and Oloumi-Sadeghi, 1991). However, crop rotation is now far less effective because of the existence of a WCRW soybean rotational variant primarily in Eastern Illinois and Western Indiana, that oviposits in soybean fields (Levine and Oloumi-Sadeghi, 1991) and of a NCRW extended diapause (2 year extended) variant, primarily in parts of Minnesota, Iowa, and South Dakota (Krysan et al., 1996). In addition, CRW has developed resistance to methyl parathion and carbaryl, both adulticides used in rescue treatments (Meinke et al., 1998). Therefore, growers have become increasingly dependent on chemical pesticides to limit CRW losses. MON 863 CRW-protected corn offers a way to potentially control CRW behavioral variants and insecticide-resistant populations more effectively than through the use of chemical pesticides for CRW and still utilize effective corn-soybean (or other crop) rotations. MON 863 corn will likely reduce or eliminate the use of certain CRW insecticides (see discussion below).

MON 863 gives growers equal or higher yields than use of chemical pesticides, while requiring less input of time and other resources. Preliminary results put this yield benefits at 1.5-4.5% (Mitchell, 2002). For a reasonable range of prices and yields, the value of this yield benefit to growers is $4-$12/A relative to the use of a soil-applied insecticides and depending on the CRW pressure.

Farmers were surveyed (Alston et al., 2002) to determine major factors that would be important to them in deciding whether to plant a transgenic corn with CRW resistance, such as MON 863, in place of their current corn. In addition to economic considerations, the farmers indicated the following non-monetary benefits would also be important.

- Safety of not handling a toxic insecticide
- Easy to use and handle
- All-in-one-product insect control
- Saving time and labor
- Better pest control

Farmers were especially interested in minimizing health and environmental effects of the pesticides they use and prefer a general use product over a restricted use product if cost and performance are comparable. Again, the survey in Alston et al (2002) indicates that farmers will favor the pesticide that minimizes adverse effects on the environment.

5. Efficacy of Event MON 863 (MRID#s 453613-03 and 455382-07)

Based on the review of the submitted field efficacy studies, MON 863 corn is as effective or more effective than chemical insecticides in protecting corn roots from CRW larval feeding damage. Chemical pesticides for CRW are usually applied to the soil at the time of planting. However, the pesticide may dissipate and no longer be effective by the time the larvae hatch. Timing is not a problem with MON 863 corn because the pesticide is incorporated within the corn roots and is produced at a relatively constant rate in growing corn. Weather is unlikely to effect the efficacy of MON 863 corn as much as it might decrease the effectiveness of the chemical insecticides. Based on the results discussed below, the extent of root damage sustained by MON 863 was less than that seen in the control corn, and less than or equal to the damage in corn treated with any of the other chemical pesticides used in the comparative analysis.

5.1. Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (*Diabrotica barberi*), Southern Corn Rootworm (*D. undecimpunctata howardi*), and Western Corn Rootworm (*D. virgifera virgifera*) (MRID # 455382-08)

In this experiment, Monsanto compared the relative efficacy of two transformed corn hybrids expressing the Cry3Bb protein (MON 853 and MON 863) in preventing damage from three species of corn rootworm larvae. This was accomplished by artificially infesting potted corn plants (treatments consisting of the two transformed hybrid and a non-transformed control hybrid) with eggs from each of three rootworm species. Each plant (in the V2 stage) was infested with approximately 800 eggs (6-8 plants per treatment were used). Root damage was scored using the Iowa Root Damage Rating (RDR) index (1 = no damage, 6 = extensive damage) after 3-4 weeks of larval feeding.

Results from the study showed that both MON 853 and MON 863 experienced significantly less root damage from all three rootworm species than the non-transformed control hybrid. In terms of western and northern corn rootworm damage, MON 863 had significantly less root damage (<2 RDR) than MON 853 (~ 2.3 RDR). For southern corn rootworm, there was no significant difference between MON 853 and MON 863 (RDR ~ 3.5-3.8). Southern corn rootworm damage was greater than western or northern corn rootworm damage for all treatments. It is noted that Monsanto is only commercializing Event MON 863.

5.2 Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials (MRID # 453613-03)

In this experiment, Monsanto evaluated the relative effectiveness of MON 863 and conventional pesticide treatments at preventing damage from corn rootworm feeding in field efficacy trials. The pesticides tested (all soil insecticides) included Force 3G (tefluthrin), Counter CR (terbufos), and Lorsban 15G (chlorpyrifos).

The study consisted of three separate field experiments, all of which utilized similar growth stage MON 863 hybrid and a non-transgenic control hybrid (negative MON 863 isoline). In each of the experiments, treatments were deployed using a randomized block design and were scored for root damage in late July. Root damage was assessed using the Iowa Root Damage Rating (RDR) index (1 = no damage, 6 = extensive damage, >3 = economic threshold). For the first experiment (conducted at seven different locations), treatments (MON 863, control, Force 3G, Counter CR, and Lorsban 15G) were deployed as four-row strips (4 replicates per treatment). Each plot was artificially infested with 800 rootworm eggs/foot (species not specified). In the second experiment (conducted at eight different locations), MON 863 was evaluated against Force 3G treatment and an untreated control. Treatments were deployed as single rows and were artificially infested with 1600 rootworm eggs/foot (species not specified). In the third experiment (conducted at nine test sites), treatments (MON 863, control, Force 3G, Counter CR, and Lorsban 15G) were planted in four-row strips in continuous corn acres or a corn/pumpkin trap crop (no artificial rootworm infestation was used). For all tests, RDR damage was analyzed via analysis of variance and t-tests to determine significant differences between treatments. Also, a "consistency rating" was calculated for each experiment by determining the percentage of root damage in a treatment that is below the economic threshold (RDR = 3) when the corresponding control treatment root damage is above the threshold.

The results of the first experiment showed that when summed across all test locations, MON 863 (RDR = 2.02), Force 3G (2.40), Counter CR (2.26), Lorsban 15G (2.40) experienced significantly less root damage than the untreated control (3.91), although there was no significant difference between MON 863 and the insecticide treatments. However, at three of the seven locations, MON 863 had significantly less root damage than all of the other insecticide treatments. For the second experiment, when summed across all eight test sites, MON 863 (RDR = 1.41) and Force 3G treatment (1.91) showed significantly less root damage than the untreated control (3.27). There was no significant difference between MON 863 and Force 3G, although root damage for MON 863 was significantly less than that for Force 3G at five of the test sites. In the third experiment, MON 863 experienced significantly less root damage (RDR = 1.72, summed over all nine locations) than any of the insecticide treatments or the control (all insecticide treatments had significantly less damage than the control). For all three experiments, the "consistency rating" for MON 863 was close to 100%, meaning that damage in MON 863 hybrids was almost always kept below the economic threshold when the control treatment showed damage exceeding the threshold.

Taken together, the results show that MON 863 prevented root damage from rootworm feeding as well or better than rootworm soil insecticides. Root damage ratings for MON 863 were typically between 1.2 and 2.0, a high level of control relative to untreated control hybrids. In addition, the results were generally consistent from location-to-location (test sites included plots in six separate corn-growing states).

6. Yield benefits (MRID# 456530-02)

The field efficacy data discussed above were used to estimate the yield benefit of MON 863 corn hybrids relative to nontransgenic corn hybrids without corn rootworm control and with a soil insecticide for corn rootworm control (Mitchell, 2002). Field data were collected to estimate the proportional yield loss as a function of the root rating difference (1-6 root rating scale of Hills and Peters). Three years of data (1994-1996) in 2 locations in Illinois (near Urbana and DeKalb) were used for the analysis. Data from efficacy experiments conducted in 1999 and 2000 in several locations were used to estimate the impact of event MON 863 on the root rating. Preliminary estimates using a composed error model for insect damage functions indicate that

MON 863 corn hybrids have a yield benefit of 1.5 to 4.5% relative to control with a soil insecticide and 9 to 28% relative to no control. The value of these benefits is estimated to be $4-$12/acre relative to control with a soil insecticide, depending on the corn rootworm pressure and $25-$75/acre relative to no control. Because there is a low correlation between root rating difference and yield loss, there is uncertainty in the realized yield benefit. This uncertainty is not due to MON 863 *per se*, but to the numerous environmental and agronomic factors determining a corn plant's yield and yield response to corn rootworm larval damage.

7. Grower benefits (MRID#s 456923-01, 456530-01-03, 450297-01, 455770-01)

Monsanto submitted a study entitled "An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Rootworm Resistant Varietal Technology - YieldGard® Rootworm" by Alston et al. (2002). Alston et al. (2002) examined the potential economic impacts in the U.S. of the commercial adoption of MON 863 corn (YieldGard® Rootworm technology). The model estimates the economic impacts if MON 863 corn had been available and was priced such that the technology fee per acre would be the same as for a representative conventional (non-Bt) CRW control technology. Alston et al (2002) used data from the year 2000 and made certain assumptions where necessary. For the year 2000, almost 8 million pounds of CRW insecticide costing $172 million were applied to 14 million acres (i.e., 17% of total corn acres planted). For a reasonable range of prices and yields, benefit to growers was estimated at $4 to $12/acre, depending on root cornworm pressure. They estimated one-year total benefits (in the year 2000) with 100 percent adoption of MON 863 corn in year 2000 of $460 million. This benefit includes $171 million to Monsanto and other seed companies and $231 million to farmers from yield gains, and $58 million to farmers from reduced risk and time savings, and other benefits associated with the reduced use of insecticides.

7.1. EPA projections of grower benefits and environmental benefits

Grower benefits are a theoretical construct that cannot be directly measured or monitored. They are defined as the premium a grower would pay for MON 863 or the difference between the value of MON863 and its' costs. Grower benefits can be depicted in a graph as the area above the technology fee and below the demand curve. This is where product value as measured by willingness to pay exceeds the technology fee. Grower benefit projections are best confirmed by comparing projected adoption rates with actual adoption rates given technology fees.

The factors that will influence grower demand are: CRW infested acres, comparative yields and costs of competing technologies for CRW insect control, U.S. and global market acceptance and approval, and other regulatory constraints (e.g., refuge requirements).

About 30% of the corn acreage (twenty-four million acres) was treated with 12 million pounds of insecticides to control pests over the last several years. For the year 2000, almost 8 million pounds of CRW insecticide costing $172 million were applied to 14 million acres ($12.29 per acre). The EPA estimates and projections use the submitted comparative performance studies and yield enhancements discussed in the previous section which indicate an increased yield of 1.5 to 4.5% for use of MON 863 over chemical pesticides when infestation levels are high.

7.1.1. Methodology and parameter estimates

The Agency predicted mature market adoption rates based on a demand simulation model and pricing behaviors based on revenue maximization (marginal cost = 0). The demand curve measures adoption at alternative technology fees for MON 863 corn. A discussion of the simulation model is found in Section II.E. of EPA's 2001 Bt Plant-Incorporated October 15, 2001 Biopesticides Registration Action Document (EPA, 2001). Briefly, the distribution of MON 863 perceived grower value and costs are assumed to be uniformly distributed across all infested acreage. Single parameter estimates are required for the maximum product value and cost. The maximum value (willingness to pay) is derived from estimates of 1) improvements to yield, 2) reductions in chemical costs, and 3) the perceived value of a less toxic product. The model also requires an estimate of the negative costs associated with of marketability discounts/risks, refuge requirements, or any other costs associated with this technology.

The maximum value reflects the acreage with the highest values due to greatest pest pressures and cost of rootworm control. An estimate of $15.75 is used for the model and is based on a 4.5% yield improvement on $350/acre gross income for corn, including government payments, which is characteristic of expectations for 2001. The cost savings from insecticides includes the out of pocket costs of $12.50 per acre plus a maximum of $2.50 per acre due to perceived value as a general use product with less toxic effects to the local environment. The perceived value of a less toxic product is not an out of pocket cost and is probably of lessor importance to growers. The high market share for Chlorpyrifos (25 % of the CRW market) may be due in part to the fact that it is only major alternative registered for general use (i.e., no restricted uses).

Value due to product performance (Yield)	$15.75
Value from lower chemical costs	$12.50
Value from easier and safer to use	$ 2.50
Max Value of Bt corn rootworm	$30.75

It is unlikely based on past experience with biotechnology products that European Union approval will occur in less than three years after launch (Vaughn et al., 2002). This international regulatory constraint imposes an additional cost on adoption of MON 863 corn. Just as was done for Roundup Ready® corn, until full European (or global) regulatory approval occurs, Monsanto plans to continue its channeling program with growers, dealers, and grain handlers to help ensure that MON 863 corn is directed into appropriate global markets (markets with regulatory approval). The simulation model can be used to assess the impact of access to global markets. The negative costs associated with limited marketability is reflected by the percent of growers who would not use MON 863 even if there was no technology fee. That is, adoption would not be 100% even if MON 863 is given away. Based on the results of a Survey on grower attitudes toward GMO's (genetically-modified organisms) conducted by the American Corn Growers Association, sixteen percent of respondents stated they would not be willing to grow more non-GMO corn varieties (Alston et al., 2002). The sixteen percent of growers is consistent with a maximum costs of $10 per acre as compared to a maximum cost of $5 per acre the 9% (91% adoption) at $0/acre technology fee.. A 16% removal from the target market would reduce adoption rates from 43% to 35% which would translate to lower grower benefits and less use reduction.

The demand curve and derived marginal revenue curve provide a basis for predicting a technology fee. The estimate of $15 per acre technology fee is based on revenue maximization behaviors which is equivalent to profit maximization if marginal cost is zero. The actual technology fee would vary from this estimate based on licensed seed companies perceptions of the demand curves for specific hybrids and marginal costs associated with marketing and sales.

EPA's economic assessment and eleven (11) year projection of aggregate grower benefits is based on current chemical prices of alternatives. It does not anticipate or include any price changes from competing technologies as MON 863 corn is introduced. It does not anticipate or include the effects of new active ingredients registered for corn rootworm.. The economic assessment is limited to grower benefits and does not estimate the reduced cost passed through to final consumers (though in the long run, economic theory suggests that the 2% improvement in returns on gross revenue would be passed through to consumers). No assessments are made of impacts to foreign trade or agricultural practices. MON 863 corn may lower the costs of rootworm control and therefore have some effect on acres grown to continuous corn which would increase pest pressures and reduce the environmental benefits of MON 863 (UCS 2002).

7.1.2. Corn Rootworm (CRW) infested acres

Scouting for the range and level of infestation is done by measuring the density of adult beetles and larvae. Gray (2000) noted that CRW infested acres are increasing due to the geographical expansion of the WCRW soybean variant. Based on both the likely geographic spread of the WCRW soybean variant and the NCRW extended diapause variant, it is likely the total infested acres will move from approximately 28 million acres to closer to 39 million acres in 13 years. This assessment projects the range of infestation to increase uniformly by 2.6% per year and the density to remain such that only one half of the acreage infested is above the economic threshold. To the extent that market forces reduce the economic threshold (increased corn prices, increased yields or reduced cost of CRW control), acreage adoption and conventional insecticide use would be higher than currently forecast and the environmental and grower benefits of MON 863 would also be higher than projected in this review.

EPA has considered the rate of increase of CRW infested aces as input into its simulation model that was used to predict technology fee, adoption rates, and grower benefits of MON 863 corn.

7.1.3. MON 863 corn hybrid supply

Adoption of MON 863 corn (acres) is dependent on supply as well as demand. The supply is constrained by corn seed hybrid availability; both for a single hybrid as well as the total number of hybrids available. The commercial hybrid development process requires sequential development that will take several years after commercial launch.

In the first two to three years after commercial launch, adoption of MON 863 corn is predicted to be relatively slow because there will only be a limited number of MON 863 corn seed hybrids available, grower acceptance, price, and global market approval of the technology. Monsanto has projected that MON 863 corn adoption will be similar to Roundup Ready® corn in that it will not be available in Pioneer or Syngenta brands nor have European Union approval at the time of launch (Vaughn et al., 2002). Roundup Ready® corn had approximately 1% (790,000 A), 2.5% (2 million A), and 5% (4 million A) acreage penetration in percent of total corn acres in year 1, 2, and 3 from commercial release, respectively. These data were used by EPA in its economic analysis.

7.1.4. Estimating the demand curve for MON 863

The demand curve for MON 863 for year 2013 is shown in Table 7. It is based on a simulation of adoption at alternative technology fees for MON 863 as described in section 7.1. Marginal revenue is computed using a technology fee of $15 based on revenue maximization. It is based on pricing behavior where the marginal costs of increasing seed production are negligible (assumes that all seed hybrids are in place). It is the last point where marginal revenue is positive (see bolded line in Table 7 below). The total revenue with a $15 technology fee is $252 million for 16.9 million acres of MON 863 corn planted in the year 2013. Actual technology fees are certain to vary from this estimate. At a $15 technology fee, MON 863 adoption is predicted to be 43% of infested acreage. If only 50% of infested acreage is treated, then only 7% of infested acreage will still be treated by conventional chemical controls (not including any refuge acres required as part of an Insect Resistance Management plan).

Table 7. Simulated demand curve for the year 2013.

Tech Fee Schedule ($)	Percent Adoption (Model Calculation)	Acres Adopted (X 10^6)	Total Revenue (X 10^6)	Marginal Revenue (X 10^6)	Marginal Revenue per Acre ($)
27	5%	1.95	52.65		
24	14%	5.46	131.04	78.39	22.33
21	23%	8.97	188.37	57.33	16.33
18	34%	13.26	238.68	50.31	11.73
15	**43%**	**16.77**	**251.55**	**12.87**	**3.67**
12	53%	20.67	248.04	(3.51)	(0.90)
9	63%	24.57	221.13	(26.91)	(6.90)

6	72%	28.08	168.48	(52.65)	(15.00)
3	83%	32.37	97.11	(71.37)	(16.64)
0	91%	35.49	0.00	(97.11)	(31.12)

7.1.5. Projecting grower benefits

Grower benefits are calculated as the sum of the difference between what the grower is willing to pay and the actual technology fee. The EPA simulation model computes the average gross benefits for adopters and Bt-related costs due to MON 863 corn adoption. The estimated net benefits per acre are $6.56 are based on a $15 technology fee (see Table 7 above). The estimated gross benefits (primarily, yield and insecticide cost reduction) per acre for adopters are $23.94 per acre and estimated Bt-related costs for adopters are $2.38 per acre.

The annual change in infested acres, adoption, conventional chemical use and associated grower benefits are projected for each year from 2003 to 2013 (Table 8 below). Projected acres infested and conventional chemical treatments are based on growth rates for infested acreage with a fixed treatment percentage of 50% of the total projected CRW infested acres.

Table 8. Projected acreage infested, MON 863 adoption and conventional treatments 2003 to 2013

Year	Acres Infested (X 10^6)	Acres treated (X 10^6)	MON 863 acres (X 10^6)	Conventional treatments (X 10^6)
2000	28.0	14.0	0.0	14.0
2002	29.5	14.7	0.0	14.7
2003	30.2	15.1	1.0	14.1
2004	31.0	15.5	2.5	13.0
2005	31.8	15.9	4.0	11.9
2006	32.6	16.3	6.0	10.3
2007	33.5	16.7	7.2	9.5
2008	34.3	17.2	8.6	8.5
2009	35.2	17.6	10.4	7.2
2010	36.1	18.1	11.9	6.1
2011	37.1	18.5	13.7	4.8
2012	38.0	19.0	15.8	3.2
2013	39.0	19.5	16.8	2.7
Annual growth rate	**2.58%**	**2.58%**		**-14.36%**

Annual grower benefits (see Table 9) are based on a constant $6.56 per acre, and the growth in total annual benefits are due to the availability of hybrid seed containing Cry3Bb over a greater areas of CRW infestations. Actual grower benefits may be higher in the early years if supply is first available in those areas with highest CRW pest pressure.

The cumulative sum of the grower benefits for the first three years (2003 to 2005) is $49.2 million and for eleven years (2003 to 2013) is $642.7 million (Table 9). The discounted aggregate benefits for year 2003 to 2013 are $385.31 million assuming a discount rate of 7%. The 7% discount rate represents the Office of Management and Budget rate (see Circular No. A-94, Transmittal Memo No. 64, October 29, 1992), a relatively risk-free rate of return similar to that assumed for a long-term Treasury bond. The discount rate is defined as the interest rate used in calculating the present value expected yearly for benefits and costs.

Table 9: Annual Grower Benefits of MON 863

Year	Target Acres ($X 10^6$)	Adoption Acres ($X 10^6$)	Grower Benefits ($\$ X 10^6$)
2003	2.3	1.0	6.6
2004	5.8	2.5	16.4
2005	9.3	4.0	26.2
2006	14.0	6.0	39.4
2007	16.7	7.2	47.2
2008	20.1	8.6	56.7
2009	24.1	10.4	68.0
2010	27.7	11.9	78.2
2011	31.9	13.7	90.0
2012	36.7	15.8	103.5
2013	39.0	16.8	110.5
Cumulative		**98.0**	**$ 642.7**

7.1.6. Projecting chemical use with MON 863 (MRID#s 456530-01 and 450297-01)

The insecticides used to control corn rootworm in conventionally grown (non-Bt) corn consist mainly of organophosphates (9), carbamates (3), synthetic pyrethroids (6), and phenyl pyrazole (1) classes of chemistry (see Table 1 above). Table 10 shows that there have been significant shifts in the use of insecticides. Synthetic pyrethroids have increased at the expense of organophosphates and carbamates. The clear shift is away from OP insecticides and toward synthetic pyrethroids, especially the effective, relatively new product tefluthrin, now the market leader (Benbrook, 2002). Fipronil was introduced in 1998 and accounts for the other category. Table 11 projects future acre treatments by chemical class using past trends and the projected conventional treatments shown in Table 8.

Table 10: Historical market shares for Corn Rootworm

Percent of total acre treatments

Chemical class	1995	2001
Carbamate	4.5%	2.1%
Synthetic Pyrethroid	21.9%	41.0%
Organophosphate	73.4%	45.8%
Other	0.1%	11.0%
total	100.0%	100.0%

Table 11: Projected treatments for Corn Rootworm

Millions of acre treatments for Corn Rootworm

Chemical class	2002	2003	2004	2005	2006	2007
Carbamate	0.3	0.3	0.2	0.2	0.2	0.1
Synthetic Pyrethroid	6.2	6.2	5.9	5.6	5.0	4.8
Organophosphate	6.5	6.0	5.3	4.6	3.8	3.3
Other	1.7	1.7	1.6	1.5	1.4	1.3
MON 863	0.0	1.0	2.5	4.0	6.0	7.0
Total CRW-treated	14.7	15.1	15.5	15.9	16.3	16.5

Table 12: Projected use reduction associated with MON 863

Millions of acre treatments for Corn Rootworm

Chemical class	2002	2003	2004	2005	2006	2007
Carbamate	0.0	0.0	0.0	0.1	0.1	0.1
Pyrethroid	0.0	0.4	1.1	1.9	2.9	3.5
Organophosphate	0.0	0.4	1.0	1.5	2.2	2.5
Other	0.0	0.1	0.3	0.5	0.8	0.9
total reduction	0.0	1.0	2.5	4.0	6.0	7.0

These pesticides have varying application rates and many are toxic to humans and non-target wildlife and have restricted use or specific, mandatory mitigation measures to minimize exposure. The average active ingredient rate applied (lb/A) has been steadily decreasing reflecting the shift from OP's and carbamates to synthetic pyrethroids and fipronil. Rates have gone from an average of 0.7 lb/A in 1995 to 0.4 lb/A in 2001. The application rates shown in Table 1 for terbufos, chlorpyrifos, carbofuran, tebupirimfos, and phorate are closer to 1 lb/A. Synthetic pyrethroids and fipronil, for example, are newer chemistries that are used at 0.1 (or less) lb/A. The use reductions shown in Table 12 indicate that as MON 863 CRW-protected corn adoption increases in the next five years, acre treatments will be reduced for all currently registered CRW insecticides. The greatest use reductions are seen in both the organophosphate and synthetic pyrethroid classes. In 2005, approximately 1.5 million acre treatments of organophosphate insecticides, 1.9 million acre treatments of synthetic pyrethroid insecticides, 0.1 million acre treatments of carbamate insecticides, and 0.5 million acre treatments of other chemical insecticides including members of the phenyl pyrazole class (e.g., fipronil) will be reduced based on 2003 figures. In 2007, the extent of insecticide use reduction will be even greater, approximately 2.5 million acre treatments of organophosphate insecticides, 3.5 million acre treatments of synthetic pyrethroid insecticides, 0.1 million acre treatments of carbamate insecticides, and 0.9 million acre treatments of other chemical insecticides are expected to be reduced.

7.2. Comparing estimates of grower benefits from other studies

Reported estimates may differ with respect to the entities included as well target year. Some include the grower and chemical producer and reflect the total societal value of MON 863. EPA's assessment is limited to grower benefits. Estimates made by Alston et al. (2002) are based on an ex ante assessment assuming that MON 863 was available in the year 2000. It is necessary to adjust estimates to the extent possible to create valid comparisons.

The one-year total benefits (in the year 2000) with 100 percent adoption of MON 863 corn in year 2000 of $460 million (Alston et al. 2002). This benefit includes $171 million to Monsanto and other seed companies and $231 million to farmers from yield gains, and $58 million to farmers from reduced risk and time savings, and other benefits associated with the reduced use of insecticides. The EPA assessment for year 2013 is based on a higher level of infested acreage. Adjusting Alton et al's analysis of the ex ante total benefits for the year 2000 of $460 million to the year 2013 by an additional 39% gives $640 million in total benefits.

The EPA estimate of total benefits can be calculated assuming a zero technology fee. This is essentially the total area under the demand curve. Total benefits would be $507 million in 2013. This compares with Alston et al's adjusted estimate of $640 million total benefits.

In a separate analysis, Gray (2000) states that if farmers invested $400 million in this technology (technology fees are assumed to $15 per acre), these resources would prevent an economic loss of approximately $600 million, for a net gain of $200 million to farmers. Adjusting this estimate to coincide with infestation levels in 2013 (a 39% increase) provides and total benefits of $834 million.

EPA's estimate of total benefits in 2013 of $507 million in 2013 is 20% lower than Alston et al.'s projections and 40% lower than Gray's projections.

8. Suggested measures to monitor environmental and grower benefits

The amount of use reduction attributed to MON 863 cannot be directly observed. For example, if the economic threshold for CRW treatment is reduced by the increased competition created by MON 863, then total infested acres treated would increase. The effect of MON 863 on chemical use reduction would be less then 1 acre per adopted acre of MON 863. A survey of growers who adopted MON 863 would be helpful to directly estimate use reduction.

Translating the environmental benefits of use reduction is a topic that is given increased attention for the purpose of strategic planning and measuring results. Measures most likely affected by the reduction in cotton insecticide use are reported incidents to workers, accidental spills, and mortality to non target wildlife.

EPA Environmental Fate and Effects Division in the Office of Pesticide Programs has identified the most toxic active ingredients to birds, based on risk assessments of based on all available information. The list contains 10 insecticides currently being used on agricultural crops: aldicarb, methyl parathion, dicrotophos, carbofuran, phorate, oxamyl, diazinon, disulfoton, methamidophos, and ethoprophos. Methyl parathion, carbofuran, phorate, diazinon, and ethoprophos are active incredients registered as formulated products for the control of corn rootworm (i.e., alternatives to MON 863). The use of methyl parathion, carbofuran, and phorate for corn rootworm control accounts for 1.2 million acres which is 6.6% of the total use of the ten insecticides on all agricultural crops. Thus, MON 863 alone can have a significant impact on reducing the use of insecticides posing the highest risk to birds. Data are not currently available to estimate exactly the impact, but additional data may be collected during the time of the conditional registration which would be useful to determine the impact of Bt corn on birds and bird population such as percent of invasive species, native species of management concern, changes in types of and/or abundance of bird species, etc.

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